IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Karl-Lutz Lauterjung §

Serial No.: 08/878,908 §

Filed: June 19, 1997 §

For: PROSTHETIC REPAIR OF BODY PASSAGES §

Group Art Unit: 3738

Examiner: P. Prebilic

DB

#24

Atty. Docket No.: SULZ-0005-US

Board of Patent Appeals & Interferences
Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

Sir:

Applicant respectfully appeals from the final rejection mailed June 22, 2000.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee Sulzer Vascutek Ltd.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF THE CLAIMS

Claims 32, 33 and 36 are allowed. Claims 21-25, 28 and 63-65 are rejected.

IV. STATUS OF AMENDMENTS

All amendments have been entered.

11/07/2000 GTEFFERA 00000013 08878908

01 FC:120 310.00 OP

Date of Deposit: October 25, 2000
I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Commissioner for Patents, Washington, DC 20231.

Sherry Tipton

Sherry Tipton

V. SUMMARY OF THE INVENTION

As a result of arteriosclerosis, portions of blood vessels may become weakened and extremely dilated. These dilated vessels may be treated by bridging the dilation or weakened extended area using a vascular tubular prosthesis. In this way the diseased portion of the vessel is effectively isolated from the pressure inside blood vessels.

Vascular tubular prostheses may be inserted into the diseased portion of the vessel by surgically opening the vessel and suturing the prosthesis into position. However, it may be preferred to insert the prosthesis from a remote opening, such as the femoral artery, adjacent the groin, using a catheter system. This is because the elimination of the need to open a major body cavity may diminish the potential surgical complications.

Generally, it is desirable to insert the prosthesis, using a catheter, in a collapsed or compressed condition and then to expand the prosthesis when in position. One reason for this is that it is desirable to avoid substantially occluding the blood flow during the insertion process. Therefore, by collapsing the prosthesis, the prosthesis may be readily positioned inside the vessel, in some cases without substantially occluding the blood flow. See specification at page 1, line 6 through page 2, line 7.

While a wide variety of solutions have been proposed to the problem of effectively bypassing diseased tissue, various existing prosthetic device designs may have certain deficiencies. For example, in some cases, the neck portion on either side of the diseased vessel portion may be relatively short. This makes it difficult for prosthetic devices to adequately engage the narrow neck on either side of the aneurysm.

In addition, some of the existing prostheses may cause blockage of the blood flow during insertion of the prosthesis, which can have physiologically adverse affects. Still another issue is

that many existing prostheses do not adequately seal against the internal surface of a vessel, allowing leakage of blood past the prosthesis into the region between the prosthesis and the weakened blood vessel. The consequence of this type of leakage can be traumatic. See specification at page 2, line 8 through page 3, line 9.

An annular, resilient clamping ring 30 may be formed of a plurality of strands 32 of resilient wire, as shown in Figure 1. One embodiment of the ring 30 may be formed by wrapping a single length of wire around a mandrel (not shown) having a central axis "C" and then securing the strands into a bundle using ties 34.

The ring 32, before compression, may have a diameter, D_K, which is considerably greater than the diameter, D_R, of the body passage 36 to be treated. As indicated in Figure 1, two diametrically opposed points "A" on the undeformed ring 30 may be deflected towards one another. As indicated by the arrows, this causes the ring 30 to fold along its diametric axis "B". In this configuration, the ring 30 may be inserted into the body passage 36 in a reduced cross-sectional configuration.

As a result of the folding along the diametric axis "B", the loops 38, which include the folded tips "A", extend proximally relative to the points "B" which are along the diametric axis of folding. As used herein, the term "proximal" refers to the direction upstream with respect to blood flow and the term "distal" refers to the direction downstream with respect to blood flow. Specification at page 7, line 8 through page 8, line 24.

Once in position inside the body passage 36, the ring 30 makes continuous contact with the internal vessel 36 wall even through the ring 30 may take a generally sinusoidal shape. To a first approximation, the height H, indicated in Figure 2, is a quadratic function of the radial compression.

The smallest permissible bending diameter without plastic deformation, D_B, shown in Figure 2, depends on the material, the thickness of the clamping ring 30 and the individual strands 32 which may make up the ring 30. According to Hooke's law, the strands 32 can be regarded as parallelly connected springs whose deflection characteristic values are additive and whose individual low radial tension forces add up to a total tension force which depends on the number of strands 32. When the entire ring 30 is compressed, each individual strand 32 has a bending diameter approximately corresponding to the minimum bending diameter D_B of the individual strand 32.

As an approximation, the minimum bending diameter D_B is approximately ten times the wire diameter. This suggests that the ring 30 wire diameter be kept low. However, the ring's clamping force on the body passage 36 is a function of its diameter, suggesting conversely that the wire diameter be increased. This tradeoff can be optimized by using a plurality of strands 32, whose diameter controls the minimum bending diameter, to form a bundle whose composite diameter controls the clamping force. Thus a clamping ring 30 with a high tension force can be shaped to a relatively small compressed configuration. After being released from a catheter, for example having a conventional diameter of from 4 to 6 mm, the ring 30 may return to its original shape and by means of sufficient tension force, securely presses the ring 30 along the wall of the body passage 36. Specification at page 8, line 25 through page 9, line 23.

A prosthesis 40 may include an annular ring 30 and a graft 42, as shown in Figure 3. The graft 42 may be generally tubular and made of a fabric or film secured on one end to the ring 30. The graft 42 may have a diameter D_P which is smaller than the diameter D_K of the clamping ring 30. Due to the connection between the clamping ring 30 and the end of the graft 42, there is a diameter D_{KP} at the junction point between the clamping ring and the graft 42. The clamping

ring 30 may expand the end of the tubular graft 42 to a stop or deformation limit, after which no further expansion occurs. Thus, the ring 30 may expand upon the graft 42 in the region proximate to the ring 30 so that the diameter of the graft 42 gradually tapers in the region 44 down to the relatively constant diameter region 46, terminating in a free end 47. Alternatively, the graft 42 could be preformed in the flared shape shown in Figure 3.

The ring 30 can be connected with the region 44 by means of sutures or bonding. It is advantageous if the clamping ring 30 is arranged on the interior surface of the graft 42 so that when the ring 30 extends against the body passage 36 wall, the graft 42 intervenes between the passage 36 and the ring 30. Thus, it may be advantageous that the diameter D_K of the ring 30 be considerably greater than the diameter of the portion 46 of the graft 42. Specification at page 9, line 24 through page 10, line 24.

Referring to Figure 4, the prosthesis 40 may be positioned within the abdominal aorta 48 proximate to the left renal artery 50 and the right renal artery 52. The loops 38 extend past the arteries 50 and 52 while the portion 53 is located just distally of the openings to the arteries 48 and 50. Thus, as shown in Figure 5, the openings to the arteries 48 and 50 are not in any way occluded by the positioning of the annular ring 30 proximate thereto because of the generally C-shaped configuration in cross-section of the ring 30.

Because of this configuration, the ring 30 may be secured to a substantially undeformed neck region 54 of relatively short height bounding an aneurysm 55. This is because at least part of the ring 30 extends proximally beyond the neck 54 without in any way affecting the flow through the arteries 48 and 50. Moreover, because the clamping ring 30 never completely expands to its unfolded configuration (shown in Figure 1), it is adaptable to irregularly configured neck 54 cross-sections.

For example, if the neck 54 is non-circular in cross-section, the sinusoidally shaped ring 30, in compression, can adapt to the irregular body passage shape. By making the ring 30 with an uncompressed diameter (D_K) greater than the diameter of the body passage (D_R) which it is designed to engage, a continuing resilient engagement occurs between the ring 30 and the body passage 36 which may continue even if the body passage becomes distended over time. This may occur regularly due to normally pulsing blood pressure or due to vasodilatation over time.

Further by making the diameter of the ring 30 (D_{KP}) greater than the diameter of the graft 42 (D_P), the graft diameter in use will correspond closely to the compressed cross-sectional diameter (D_K) of the ring 30, in position within the body passage 36. This lessens any unnecessary bunching of the graft 42 around the neck 54. Specification at page 10, line 24 through page 11, line 25.

With the apparatus and techniques described above, it should be apparent that the prosthesis 40 may be positioned without substantially blocking the flow of blood even during the surgical procedure. Moreover, the prosthesis 40 is configured so as not to substantially interfere with intersecting vessels such as the renal arteries. At the same time a modular approach may be utilized to adjust for different physiologies. This in combination with the fact that the annular ring 30 need never extend to its fully undeformable configuration, means that it is not necessary to stock a variety of different stents. Instead, it is possible to have a relatively limited or even a single set of sizes which can be adapted to a variety of patient conditions.

Because of the fact that the rings 30 have a C-shaped configuration in position in the body passage, it is possible to locate the prosthesis in a relatively narrow neck 54 region. Since the ring 30 remains in its compressed configuration in use, it adapts for short term and long term distension of the treated passage. Moreover, because of the constantly applied spring bias

pressure of the rings 30, good sealing contact is maintained between the rings 30 (and the prostheses) and the wall of body passage even if the passage is irregularly shaped. Specification at page 18, line 18 through page 19, line 8.

VI. ISSUES

A. Do the References Cited Under § 102 Teach Folded Springs?

B. Are the Claims Dependent on Claim 21 Anticipated?

C. Is the § 102 Rejection of Claim 65 Based on Kwan-Gett Proper?

D. Is the § 102 Rejection of Claim 63 Based on Kwan-Gett Proper?

VII. GROUPING OF THE CLAIMS

For brevity on appeal, claim 21 may be grouped with claims 24, 25 and 28 and claims 64 and 65 may be grouped.

VIII. ARGUMENT

A. Do the References Cited Under § 102 Teach Folded Springs?

Claim 21 calls for a prosthesis having a pair of folded, resilient annular springs each having a first pair of loops extending in one direction and a second pair of loops extending in the opposite direction. The first and second pairs of loops are connected together. A tubular graft, connected to each spring, has a pair of free ends, the annular springs being connected to each of the free ends of the graft.

Claim 21 was rejected under § 102 as being anticipated by Lazarus and Robinson.

Claim 21 calls for a pair of "folded" resilient annular springs each having a pair of loops. The folded structure is shown for example in Figure 2 (and similarly in Figures 4 and 5) wherein the spring is folded about the bending diameter D_B.

Lazarus teaches away. As shown in Figure 6, Lazarus does not fold his end elements but instead simply compresses them radially. See also page 8, lines 8-9. The same thing is done in Robinson. That is, both Robinson and Lazarus teach springs which are compressed radially. Therefore there is no need in Robinson or Lazarus to create a folded spring.

The wire used in the references to form an annular spring may be bent but the spring itself can not fairly be described as "folded". For example, it would be unfair to argue that a sheet as a whole is not flat because its molecules are in the form of cubic crystals.

Since the cited references fail to teach a folded spring, the § 102 rejection should be reversed.

B. Are the Claims Dependent on Claim 21 Anticipated?

Claim 22, dependent on claim 21, calls for a pair of loops arranged to avoid occlusion of the renal artery, when the prosthesis is positioned in the abdominal aorta. The claim is rejected over Lazarus and Robinson under § 102. The Examiner cites the whole document "especially the figures and the 'detailed description of the invention'". No support can be found in either of the references for the claimed feature.

Claim 23 calls for the annular springs to have an unfolded diameter and the tubular graft to have a diameter less than the unfolded diameter of one of the annular springs. Again, the rejection is completely unsupported except to cite the entire document. It does not appear that there is any basis to assert that the graft has a diameter less than the unfolded diameter of one of the springs. In fact, the springs do not even have "folded" diameter so it is not even clear how to apply the claims to the reference.

Certainly, it behooves the Examiner to at least attempt to point out what would be the unfolded diameter of the springs in the cited references and how that diameter relates to the

diameter of the graft. Failing any attempt to do so (it appearing impossible to do so), claim 23 (as well as claim 21) is clearly allowable.

If the Examiner argues the wires within the prior art spring are "folded" (instead of correctly addressing the folding of the spring as claimed), he faces the daunting task of finding a diameter for such alleged "folds". Surely, it would be unfair to apply "diameter" to the annular spring as a whole and "folded" to an element within the spring.

Thus, the rejection of claim 21 should be reversed.

C. Is the § 102 Rejection of Claim 65 Based on Kwan-Gett Proper?

Claim 65 calls for a minimum bending diameter of the ring to be less than that of a solid ring of the same dimensions. Claim 65 is rejected under § 102(b) as being anticipated by Kwan-Gett.

The importance of the minimum bending diameter being less than a corresponding solid ring of the same dimensions, is explained in the specification and in the Summary of the Invention in the present Appeal Brief beginning at the top of page 5. Ideally, the minimum bending diameter D_B is important because it is desirable to keep the bending diameter as small as possible. Because the minimum bending diameter is approximately ten times the wire diameter, it would seem that the diameter of the wire strands should be kept as low as possible. However, the ring's clamping force on the body passage is a function of its diameter suggesting conversely that the wire diameter be increased. By using a plurality of strands to form the ring, the small diameter of the individual strands controls the minimum bending diameter. The plurality of strands are made up of wrappings of a strand of resilient wire as set forth in the claim.

The minimum bending diameter is controlled by the diameter of the individual wire strands while the clamping force is determined by the composite diameter of the overlapping windings of the wire. Thus, by forming a ring of a bundle of overlapping windings from a strand

of resilient wire, the minimum bending diameter of the ring may be less than that of a solid ring of the same dimensions. As a result, the resulting ring may have a small minimum bending diameter which means that the ring may be folded to a very reduced shape while having a high clamping force which means that the ring will securely press against the entire internal surface of a body passage. Nothing in Kwan-Gett suggests any such arrangement.

There is support in the specification for claim 65. The specification points out the fundamental idea that by using a plurality of strands to form the ring diameter instead of a solid ring, the resulting minimum bending diameter is controlled by the diameter of the individual strands as opposed to the composite ring diameter. See specification at page 9, lines 14-19. The specification defines the smallest permissible bending diameter without plastic deformation, D_B, as depending on the material, the thickness of the clamping ring and the individual strands which make up the ring. See page 8, lines 30-33. At page 9, lines 5-8 it is explained that each individual strand 32 has a bending diameter approximately corresponding to the minimum bending diameter, D_B, of the individual strand. Finally, at page 9, lines 17-19 it is stated that "thus a clamping ring 30 with a high tension force can be shaped to a relatively small compressed configuration."

The relatively small compressed configuration is obviously a function of its minimum bending diameter. The term "relative" indicates that the bending diameter is smaller than something else and that something else necessarily must be a solid ring not made up of strands. Therefore, it is respectfully submitted that there is adequate support for this claim limitation.

No such structure is provided in Kwan-Gett. Because Kwan-Gett has a torsion spring, the effect on minimum bending diameter of the individual flat strips can not be realized and Kwan-Gett makes no claim that minimum bending diameter is reduced.

Kwan-Gett teaches a coiled flat strip to form a stent 18 or 20. While Kwan-Gett never even addresses the stent's minimum bending diameter, it is apparent from basic physics that the flat strips would have a very large minimum bending diameter. Bending the stent 18, 20 would necessarily involve bending against the elongated width of the flat strip, which would be difficult. Kwan-Gett never even shows the springs being bent (see Figure 4). Certainly, the stent 18, 20 would be more bendable if one did not need to bend each of the overlapped flat strips against its elongated width.

Therefore, claim 65 patentably distinguishes over the art.

D. Is the § 102 Rejection of Claim 63 Based on Kwan-Gett Proper?

Claim 63 calls for a prosthesis including a tubular graft having a pair of free ends and a ring. The ring comprises a bundle of overlapping windings formed of a strand of resilient wire, the ring being located adjacent one of the free ends.

Claim 63 was rejected over the Kwan-Gett reference under § 102. Kwan-Gett shows a expanded helical wire with a graft 12.

Kwan-Gett does not use a wire. The rejection relies on the elements of the stents 18, 20 to constitute the claimed bundle of overlapping windings formed of a strand of resilient wire, located near one of the ends of the graft. The stents are torsion springs formed of a flat metal strip. See Kwan-Gett at col. 5, lines 19-22. Such a strip would not constitute the wire as claimed. A wire is a "metal that has been drawn onto a very long, very thin thread or reel, usually circular in cross-section". Webster's New World Dictionary, Second College Edition.

Thus, a flat strip does not constitute the claimed wire.

IX. CONCLUSION

Since the rejections of the claims are baseless, they should be reversed.

Respectfully submitted,

Date: 10/25/00

Timothy N. Trop
Reg. No. 28,994
TROP, PRUNER & HU, P.C.
8554 Katy Freeway, Suite 100
Houston, TX 77024-1805
713/468-8880 [Phone]
713/468-8883 [Fax]

APPENDIX OF CLAIMS

The claims on appeal are:

21. A vascular prosthesis for repairing a diseased first vessel comprising:

a pair of folded, resilient, annular springs each having a first pair of loops extending in one direction and a second pair of loops extending in the opposite direction, said first and second pairs of loops connected together, and

a tubular graft connected to each spring, wherein said tubular graft has a pair of free ends, said annular springs being connected to each of said free ends.

22. The prosthesis of claim 21, said second pair of loops are arranged to avoid occlusion of the renal arteries when said prosthesis is positioned in the abdominal aorta.

23. The prosthesis of claim 21, wherein said annular springs have an unfolded diameter and said tubular graft has a diameter less than the unfolded diameter of one of said annular springs.

24. The prosthesis of claim 21, wherein one of said annular springs is formed by a plurality of strands of resilient wire having a substantially common central axis.

25. The prosthesis of claim 24 wherein one of said springs is circular in cross-section when undeformed.

28. The prosthesis of claim 21 including a device for axially receiving a guide wire, said devices adapted to telescopically and releasably receive said guide wire.

32. A prosthesis for insertion within a body passage comprising:

a first section including a resiliently deformable first annular element and a first tubular graft that is less resilient than said first annular element, said first tubular graft having a pair of free ends and an internal surface, said first annular element connected to one of said free ends;

a second section axially aligned with said first section, said second section including a resiliently deformable second annular element, said second annular element of said second section adapted to communicate with and resiliently engage an internal surface of said first tubular graft of said first section so as to adjustably fix the second section within the first tubular graft;

a pair of relatively rigid elements defining a pair of independent passages into said free end of said second prosthesis section; and

a third and fourth prosthesis section telescopically engaging said relatively rigid elements on said free end of said second prosthesis section, each said third and fourth prosthesis sections including a pair of annular resilient deformable spring elements and a tubular graft, said spring elements attached to free ends of said tubular graft, at least one of said spring elements adapted to engage the interior of said second prosthesis section.

33. The prosthesis of claim 32 wherein said second section further includes a second tubular graft attached to said second resilient element, said second tubular graft having a pair of free ends, one of said free ends connected to said second resilient element.

36. The prosthesis of claim 32 wherein said second prosthesis section includes a graft which has one end which defines a single passage and an opposite end which defines a pair of bifurcated passages which communicate with said single passage.

63. A prosthesis comprising:

a tubular graft having a pair of free ends; and

a ring comprising a bundle of overlapping windings formed of a strand of resilient wire, said ring located adjacent one of said free ends.

64. The prosthesis of claim 63 wherein the minimum bending diameter of said ring is less than that of a solid ring of the same dimensions.

65. A prosthesis comprising:

a tubular graft having a pair of free ends; and

a ring comprising a bundle of overlapping windings formed of a strand of resilient wire, said ring secured to said graft adjacent one of said free ends thereof, wherein the minimum bending diameter of said ring is less than that of a solid ring of the same dimensions.